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Original Article

Percutaneous left atrial appendage closure in AF using Amplatzer Cardiac Plug: First single center experience from India☆

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ABSTRACT

Background: Atrial fibrillation (AF) is one of the most common arrhythmias accounting for significant mortality and morbidity, especially in elderly. Though oral anticoagulation (OAC) is an effective mode of prevention of stroke in patients of AF, bleeding complication remains a major concern. Because of these issues, a significant proportion of patients either does not receive or receive suboptimal doses of OAC.

Methods: In such patients, percutaneous left atrial appendage (LAA) closure remains an interesting option. Experience and literature of this procedure from India have been sparse. We report the first single center experience, from India, of percutaneous LAA closure with Amplatzer Cardiac Plug in 10 patients of non-valvular AF. These patients had contraindications for OAC or had high risk of bleeding or labile international normalized ratio (INR) on therapy.

Results: We successfully deployed the devices in all of the cases with no major complications perioperatively and on short-term follow-up. We also report a comprehensive review on the technique of percutaneous LAA closure using Amplatzer Cardiac Plug, including some novel modification with our experience of doing percutaneous mitral balloon valvuloplasty.

1. Introduction

Atrial fibrillation (AF) is one of the most common cardiac arrhythmias, which affects around 3–5% of population between 65 and 75 years of age. The prevalence increases to >8% in patients above the age of 80 years.[1] Ischemic stroke is the most disabling morbidity due to AF especially in elderly. Stroke risk in patients with non-valvular AF (NVAF) is around 3–5% per year. Overall AF accounts up to 30% of stroke in patients over 80 years of age.[2]

Oral anticoagulation (OAC) is the standard treatment for stroke prevention in patients with NVAF with CHA_2DS_2-VASc stroke risk score ≥ 1.[3] OAC is effective in stroke prevention, but

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increased risk of serious bleeding episodes prevents many patients from taking this therapy.[4,5] Percutaneous left atrial appendage (LAA) occlusion is a new and emerging therapy, which provides an alternative to OAC in patients with high stroke risk and contraindication to OAC. The rationale behind LAA occlusion using a device is that >90% of thrombi in patients with NVAF are located in LAA, whereas in patients with valvular AF, only 60% of thrombi are located in the LAA.[6] Currently, LAA closure has been given a Class IIb recommendation in AHA/ESC 2014 guidelines. There are number of devices available at present, WATCHMAN device and the AMPLATZER CARDIAC PLUG (ACP) to name a few. The experience of this procedure is limited in India, and there are no published data from our country regarding this evolving therapy. Thus, we intend to share our experience of LAA closure from a single center in India with relevant review of literature through this report.

2. Case selection

Between December 2014 to February 2015, 10 consecutive patients of NVAF who were currently on OAC (warfarin or novel anticoagulants) but had high risk of bleeding or labile international normalized ratio (INR) on therapy or discontinued treatment with OAC due to potential risk of bleeding were enrolled for the procedure. The baseline characteristics and risk factors of the patients are shown in Table 1. All the patients had CHA_2DS_2-VASc risk score of >1. Their bleeding risk was high as calculated by the HAS-BLED score, which was 3 in all the cases. Four of the patients had labile INR on treatment. We enrolled these patients for percutaneous LAA closure using Amplatzer Cardiac Plug (ACP 1).

3. Procedure and device implantation

3.1. *Imaging during the procedure*

A pre-procedure transthoracic echocardiography (TTE) was done in all the cases to assess the left ventricular function and any contraindication to device closure. Ideally a pre-procedure transesophageal echocardiography (TEE) should be done to assess the LAA anatomy and feasibility for device occlusion. TEE was also done during the procedure to assess LAA anatomy, size of the ostium, and size of landing zone for the device lobe, which are needed to determine the size of the device. Ostium of LAA is measured at the level of left circumflex artery (LCX) and the left upper pulmonary vein (LUPV). The measurement of landing zone is taken 10 mm inside the ostium perpendicular to neck of LAA (Fig. 1). The size of the landing zone determines the size of the lobe of ACP to be

Table 1 – Patients baseline profile, TEE and angiogrpahic measurements of LAA and size of the device selected.

	Age (years)/ sex	Risk factors apart from age	CHA_2DS_2-VASc risk score	Bleeding risk (HAS-BLED score)	LAA ostium on TEE (short axis) (mm)	Size of landing zone on tee (short axis) (mm)	Angiographic measurements of landing zone in RAO cranial view (mm)	Size of the ACP device selected for LAA closure (mm)
Case 1	77/male	Hypertension	3	3 (high risk of bleeding)	22.7	19	20	22
Case 2	67/female	Hypertension	3	3 (high risk of bleeding)	20.4	16.8	18	22
Case 3	68/male	Hypertension	2	3 (high risk of bleeding)	31.6	24.6	24	30
Case 4	69/female	Diabetes, hypertension	4	3 (high risk of bleeding)	21.7	17.9	20	24
Case 5	58/female	Hypertension	2	3 (high risk of bleeding)	22	17.6	18	22
Case 6	73/female	Hypertension	3	3 (high risk of bleeding)	22.8	20	17	24
Case 7	67/female	Hypertension	3	3 (high risk of bleeding)	25.6	22.8	23	26
Case 8	71/male	Congestive cardiac failure	2	3 (high risk of bleeding)	33.10	24.18	24.18	28
Case 9	68/female	Hypertension	3	3 (high risk of bleeding)	23.6	18.25	15.55	22
Case 10	75/female	Hypertension	4	3 (high risk of bleeding)	24.1	19.3	18	22

CHA_2DS_2-VASc – stoke risk scoring system includes **C**ongestive cardiac failure (1 point), **H**ypertension (1 point), **A**ge ≥ 75 years (2 point); **D**iabetes (1 point); previous **S**troke or transient ischemic attacks (2 point), **V**ascular disease (1 point), **A**ge 65–74 (1 point) and female **S**ex (1 point); HAS-BLED-BLEEDING RISK SCORE includes **H**ypertension (uncontrolled systolic blood pressure >160 mm Hg) (1 point), **A**bnormal renal and/or liver function (1 point), previous **S**troke (1 point), **B**leeding history or predisposition (1 point), **L**abile INR (1 point), **E**lderly (1 point), and concomitant **D**rugs and/or alcohol excess. **TEE** – transesophageal echocardiography; **LAA** – left atrial appendage; **ACP** – Amplatzer Cardiac Plug; **RAO** – right anterior oblique.

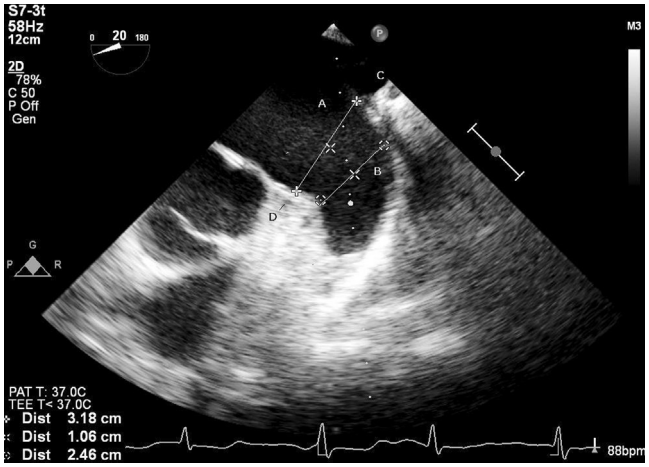

Fig. 1 – Transesophageal echocardiography showing the LAA and the measurements to be taken (A – ostium of LAA; B – measurement of the landing zone which is 10 mm inside the ostium perpendicular to neck of LAA; C – LUPV; D – LCX).

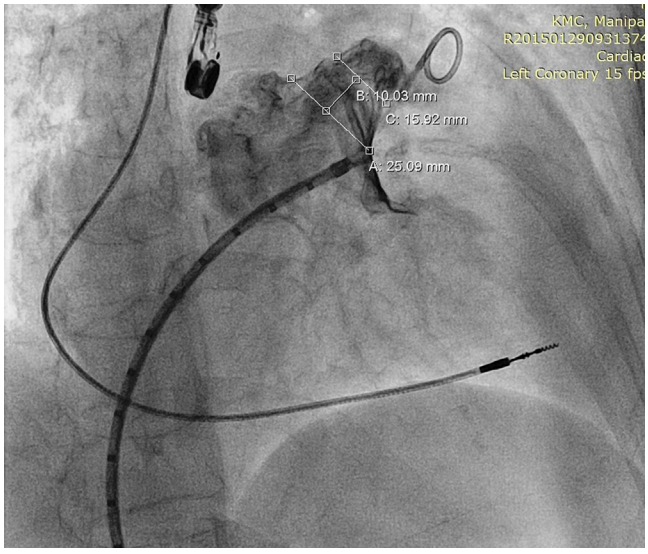

Fig. 3 – Angiography in right anterior oblique view opacifying the LAA and the measurements to be taken (A – ostium of the LAA; B – distance between the ostium and the landing zone for the device in LAA (10 mm); C – measurement of the landing zone for the lobe of the device).

used. The respective dimensions of all the cases are shown in Table 1.

3.2. *Access and transseptal puncture technique*

All the procedures were done under general anesthesia after taking informed consent. Right femoral vein was cannulated using Seldinger technique. Transseptal puncture was done with the help of Brockenbrough septal puncture needle, under TEE guidance. The site of the transseptal puncture differs from that of the balloon mitral valvotomy (BMV), in that it is done posterior and inferior to fossa ovalis in order to align the delivery sheath to LAA (Fig. 2). The Mullen's sheath is then passed over the puncture needle in the left atrium (LA). 6-Fr sizing pigtail catheter is taken inside the Mullen's sheath into LA to facilitate for angiography of LAA.

Fig. 2 – Transesophageal echocardiography-guided transseptal puncture which is posterior and inferior to the fossa ovalis (A – tenting of the atrial septum; B – brockenbrough needle).

3.3. *Angiography*

The Mullen's sheath and the pigtail are then guided into the LAA body by anticlockwise torque on the pigtail. Once the pigtail is inside the body of LAA, angiographic views in right anterior oblique (RAO) 20° and cranial 20° were taken by contrast injections through the Mullen's sheath. LAA ostium measurements and landing zone measurements were done (Fig. 3). If required, additional views such as RAO caudal were taken to delineate the LAA anatomy clearly. After taking angiographic measurements in different views and comparing it with TEE measurements, appropriate size of the device was chosen. The device selected is based on the lobe size of ACP and measurement of the landing zone. The lobe size should be 3–6 mm more than the measurements of the landing zone. The respective sizes of the devices in each of the cases are shown in Table 1.

3.4. *Technique of device implantation*

After angiography, Mullen's sheath was exchanged with an exchange length 0.035″ super stiff wire, which was placed in the LUPV. Then, an Inoue dilator was used to dilate the skin and soft tissues and the interatrial septum. This step been seldom described in any of the reviews from other countries and is a novel modification from our experience, from doing percutaneous BMV. This step of dilating the soft tissue and interatrial septum allows easy passage of the delivery sheath for device deployment. The appropriate-sized delivery sheath was then introduced over the super stiff wire up to the LUPV. The device was then loaded into delivery cable and introduced inside the delivery sheath up to the end of the sheath. The delivery sheath, which was resting in the LUPV, was then pulled back slightly, which makes it to face the LAA ostium.

The device is then pushed out of the delivery sheath till it forms a ball shape. After which, the whole system is pushed inside the body of LAA, and continuous monitoring with the help of TEE was done. Once on TEE, it is confirmed that two third of the lobe is beyond the LCX artery, an anticlockwise torque to the delivery sheath was given and device was further pushed out till the lobe of ACP is deployed. This anticlockwise torque helps to align the ACP perpendicular to neck of the LAA. The lobe should attain a shape of a tyre before further deployment of the device. Once satisfactory shape and location of the lobe are confirmed on TEE, the disk of the device was deployed by pulling back the delivery sheath and maintaining a traction on the delivery cable.

3.5. *Checklist before final release of the device (Fig. 4)*

1. Tyre shape of the lobe.
2. Good separation between the lobe and disk.
3. Disk is concave in shape.
4. Disk should seal the ostium of the LAA completely. This is confirmed by angiography via injection of contrast through the delivery sheath. It can also be confirmed by color Doppler on TEE. Jet width up to 3 mm on TEE is accepted across the device.
5. Two third of the lobe should be inside the LCX artery on TEE.
6. ACP should parallel the LAA neck.

After confirming all these points, the device is finally released by rotating the delivery cable in anticlockwise manner till the device was finally released. The delivery cable and sheath were taken out and local hemostasis was achieved by local compression at the puncture site.

In our case series, all the cases were performed by 2 operators. We did not have any screen failures. In 80% of cases (8 out of 10 cases), device was deployed in the first attempt, but in 2 cases, we had to retrieve and reposition the device. In 10% of cases (1 out of 10 cases), device was deployed in second attempt, and in 10% of cases (1 out of 10 cases), device was deployed in third attempt.

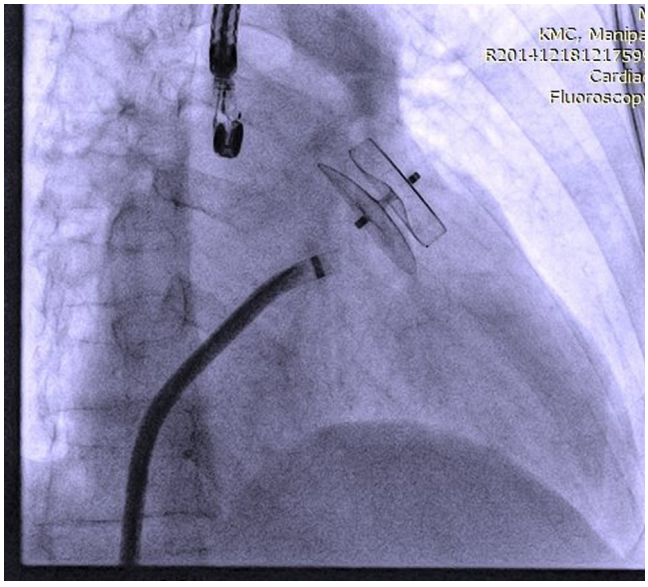

Fig. 4 – Fluoroscope image showing the final deployed device.

3.6. *Post-procedure treatment and follow-up*

Post-procedure, all patients were put on OAC with warfarin for 45 days along with single antiplatelet agent. Then, OAC was stopped and dual antiplatelet continued for six months, after which single antiplatelet will be continued indefinitely if there is no contraindication. Post-procedure TEE was done before discharge to look for early device embolization. Repeat TEE, done at six weeks, showed device in situ in all cases with no major complications. At 3rd month (8 cases) and 6th month (2 cases) follow-ups, there were no major complications and closure rates were 100% in all cases.

3.7. *Possible complications*

1. Cardiac perforation and pericardial effusion due to trans-septal puncture or due to device itself. Cardiac perforation up to 7 days is reported due to device.
2. Pericardial effusion and cardiac tamponade.
3. Device embolization (early and late).
4. Device thrombosis.
5. Stroke/TIA – thromboembolism, air embolism.
6. Vascular complications – hematoma, bleeding.

No such major or minor complications were noted during the procedure in any of our cases.

4. Discussion

First case of percutaneous LAA closure was done in 2002, after that a number of studies have been done, which shows that this strategy is safe and efficacious in indicated patients of NVAF. PLAATO was the first approved device for LAA closure, which was evaluated by 2 multicentric prospective study with positive results on 5-year follow-up.[7,8] The recently concluded randomised controlled trials like PROTECT AF and PREVAIL study, which used the WATCHMAN device, showed LAA closure to be non-inferior to OAC and had less bleeding risk when compared to OAC. These studies also showed percutaneous LAA closure to be superior to OAC in terms of stroke prevention and had a larger 'net clinical benefit' than OAC in patients with higher stroke risk.[9,10] The device which was used in our study was Amplatzer Cardiac Plug (ACP) (St. Jude). The ACP is a self-expandable nitinol device with a polyester patch within, formed by three parts: a cylindrical lobe with a fixed length of 6.5 mm, to which diameter (16–30 mm, stepwise by 2 mm) the prosthesis size refers; an occlusive disk, 4 mm larger than the 16–22 mm prosthesis, and 6 mm larger than the 24–30 mm devices; and a flexible central connector pine. There are six pairs of barbs attached to the lobe and directed to the disk, all identified by radiopaque marks, to enhance the retention of the lobe in LAA. The occlusive disk permits the complete closure of the LAA orifice by a pacifier principle, and enables this device to be useful in any anatomical variants of LAA (Fig. 5).

Recent AHA/ESC guidelines have given a class IIb recommendation for percutaneous LAA closure in patients with

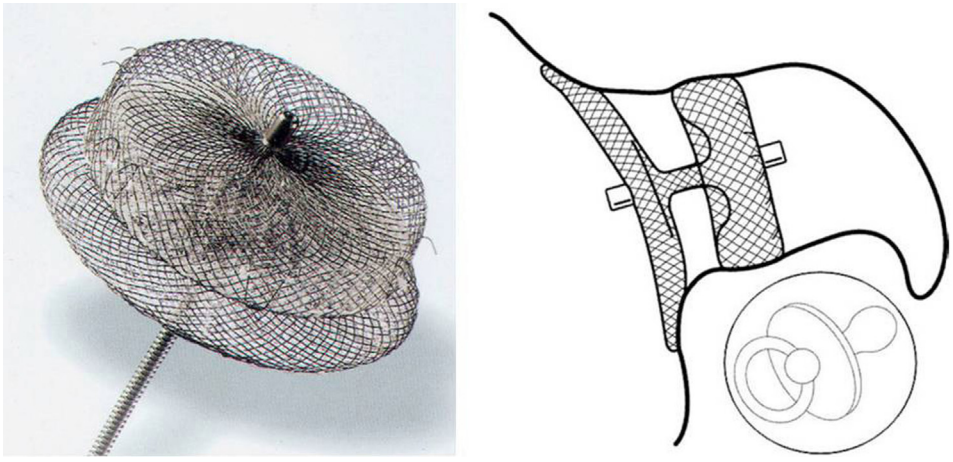

Fig. 5 – The Amplatzer Cardiac Plug and the "pacifier principle".

NVAF, who are at high risk of stroke and who also have contraindication to long-term OAC therapy. Other indications are high risk of stroke with relative contraindications to OAC therapy and patients with labile INR.

While there is considerable experience and exposure for percutaneous LAA closure outside India, there are no reported cases from India till now. Thus, through this report, we intend to share our experience of percutaneous LAA closure with ACP in 10 successful cases and to report a comprehensive review on the technique of percutaneous LAA closure using ACP, including some novel modification with our experience of doing BMV. So far, we had no complications during or after the procedure, and all cases are doing well on short-term follow-up. It is important to understand that it is still an emerging and evolving therapy, and safety is of utmost importance. Moreover, imaging with TEE during the procedure is an integral part of performing successful percutaneous LAA closures. The anatomy of LAA is highly variable and can offer many procedural difficulties and challenges. Finally, we need further studies and long-term follow-up to refine patient selection, to select an ideal post-procedural antithrombotic therapy, and to document long-term efficacy of percutaneous LAA closure.

Our short-term experience with LAA closure with ACP suggests that it is a safe and feasible procedure with encouraging short-term outcomes. It may provide alternative strategy to OAC therapy in patients with AF-induced high stroke risk and intolerance for OAC. Further, large-scaled trials are needed to confirm the efficacy of this procedure.

Conflicts of interest

The authors have none to declare.

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